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JUL 1 3 2001

Attachment 10

510(k) Summary

June 1, 2001

1. Submission Applicant & Correspondent:

Name:	Zynergy CardioVascular, Inc.
Address:	298 Fernwood Ave.
	Edison, NJ 08837
Phone No.:	(732) 225-3800
Contact Person:	Ms. Jing Zhang

2. Name of Device:

Trade/Proprietary/Model Name:	Zynergy Z5000 Electrophysiology Catheter With Z9000 Accessory Cable
Common or Usual Name:	Electrophysiology Catheter
Classification Names:	Electrode Recording Catheter

3. Devices to Which New Device is Substantially Equivalent:
Zynergy Z5000 Electrophysiology Catheter With Z9000 Accessory Cable is substantially equivalent to Zynergy Zolution Electrophysiology Catheter Model Z5000 and Cable Model Z9000 as described in 510(k) K991060, which is cleared by the FDA on April 6, 2000.

4. Device Description:
Same as the predicate Zynergy Zolution Electrophysiology catheter, the Zynergy Z5000 Electrophysiology catheter is comprised of a radiopaque tubing reinforced with stainless steel braiding. The soft tip is fitted with electrodes in varying sizes and configurations. The back end of the catheter is comprised of an electrical connector.

5. Intended Use of the Device:
Zynergy Z5000 Electrophysiology Catheter With Z9000 Accessory Cable is indicated for temporary use in electrophysiology studies for intracardiac simulation and/or ECG recording.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:
The Zynergy Z5000 Electrophysiology Catheters have identical indicated use, use the same operating principle, have similar size ranges, incorporate the same basic catheter design and technological characteristics, and are packaged and sterilized using the same materials and processes (ETO sterile and pyrogen free) as the predicate Zynergy Zolution catheters.

The major differences between the Z5000 catheter and the predicate device are in the catheter's main body tube material and electrode material. These changes do not raise any new issues of safety or effectiveness as demonstrated by the biocompatibility test results and comparable results from the design verification testing.

7. Tests and Conclusions:
Extensive functional and performance testing, and biocompatibility testing were conducted to assess the safety and effectiveness of the Zynergy Z5000 Electrophysiology Catheter. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2001

Mr. Jing Zhang
Manager, Regulatory Affairs
Zynergy CardioVascular, Inc.
298 Fernwood Avenue
Edison, NJ 08837-3839

Re: K011847
Trade Name: Zynergy Z5000 Electrophysiology Catheters with Z9000 Accessory Cables
Regulation Number: 870.1200
Regulatory Class: II (Two)
Product Code: DRF
Dated: June 1, 2001
Received: June 13, 2001

Dear Mr. Zhang:

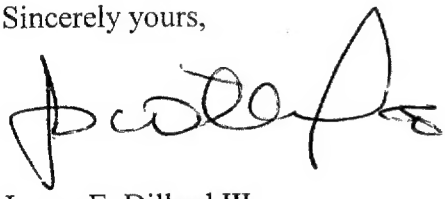
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K011847

Attachment 3

Indications for Use Statement

510(k) Number
(if known)

Device Name Zynergy Z5000 Electrophysiology Catheter With Z9000 Accessory Cable

Indications for Use Identical to the indications of the predicate Zynergy Zolution catheters and cables cleared through 510(k) K991060, Zynergy Z5000 Electrophysiology Catheter With Z9000 Accessory Cable is indicated for temporary use in electrophysiology studies for intracardiac simulation and/or ECG recording.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ——
(per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011847